K052594(p1of2)

FEB 1 0 2006

510(k) Summary

Name of Device:
Trade name: WillCare GW-1020
Common name: Infusion pump
Device Class: II
Product Code: FRN
Regulation number: 21 CFR 880.5725

Name of Predicate Device:
Trade name: Minimed Model 404-SP
510(k) number: K922670
Common name: Infusion pump
Device Class: II
Product Code: FRN
Regulation number: 21 CFR 880.5725

Submitted by:
ICU Medical, 951 Calle Amanecer, San Clemente, CA 92673

Description:
The WillCare GW-1020 is an electromechanical infusion pump designed for use with therapies requiring accurate delivery of small volumes of medication. The pump delivers fluid with a resolution of 0.002 milliliters and allows for continuous delivery, for intermittent delivery, or for a combination of both. Components of the pump that are essential for effective operation are listed in the operators manual (Components – Basic Kit), and must ONLY be supplied by ICU to ensure proper and safe operation.

Indication for use:
The WillCare GX-1020 external pump is indicated for intravenous infusion of medicinal products at set and variable rates.

Technological Characteristics to the Predicate Device:

Item	WillCare GX-1020	MiniMed 404-SP
Size	3.4 x 1.7 x .7 inches	2.0 x 3.4 x 0.8 inches
Battery life	4 days minimum at 0.800 ml/hr 6 weeks minimum at 0.002 ml/hr	2 days minimum at 0.720 ml/hr 6 weeks minimum at 0.002 ml/hr
Rate mode	Maximum – 0.800 ml/hr Minimum – 0.020 ml/hr Increment – 0.002 ml/hr Default – 0.050 ml/hr	Maximum – 0.720 ml/hr Minimum – 0.000 ml/hr Increment – 0.002 ml/hr

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Item	WillCare GX-1020	MiniMed 404-SP
Interval mode	Maximum – 0.998 ml/dose Minimum – 0.100 ml/dose Increment – 0.002 ml/dose Default – 0.250 ml/dose	Maximum – 0.998 ml/dose Minimum – 0.000 – 0.250 ml/dose Intervals – 5, 10, 15, 20, 30, 45, 60, and 90 minutes and 2, 3, 4, 6, 8, and 12 hours
Demand dose	Maximum – 0.998 ml/dose Minimum – 0.100 ml/dose Increment – 0.002 ml/dose Default – 0.250 ml/dose	Maximum – 0.998 ml/dose Minimum – 0.002 ml/dose
Syringe capacity	3.0 ml	3.0 ml
Power source	3.6V DC (1/2 AA)	3 standard 1.5 V silver oxide watch batteries
Alarms	Low battery Low volume Safety alarm High pressure	Low battery Safety/program alarm Empty syringe Occlusion Maximum total exceeded
Physical Characteristics	DC Motor Reduction Gear Drive	DC Motor Reduction Gear Drive
Other features	Lock mode	Three lock levels

Performance Testing:
Safety compliance testing (SCR043S-004) has been conducted to demonstrate device reliability and conformance to IEC 60 601-2-24. The results are in conformity to the technical specifications and all referenced standards. Detailed testing information is included in attachments H, I and J of this submission.

Conclusions:
Results of testing and comparisons to the predicate device show that the WillCare GX-1020 is substantially equivalent to the MiniMed 404-SP predicate device. The minimum demand dose of the WillCare GX-1020 is 0.100 ml/dose and that of the predicate device is 0.002 ml/dose, these differences do not impact the performance, safety or accuracy of either device, rather they are intended to be used as information to the prescribing doctor when issuing medication to a patient. Furthermore, it is concluded that the performance and accuracy of the device is as safe and effective as that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2006

ICU Medical, Incorporated
C/O Mr. Morten Simon Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1655 Scott Boulevard
Santa Clara, California 95050

Re: K052594
Trade/Device Name: WillCare GX-1020
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 26, 2006
Received: January 27, 2006

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052594

Device Name:
WillCare GX-1020

Indications for Use:
The WillCare GX-1020 external pump is indicated for intravenous and non-intravenous infusion of medicinal products at set and variable rates.

Prescription Use X AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division Sign-Off
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number K052594